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FROM	:	Oleg F. Kaplun, Esq. of Fay Kaplun & Marcin, LLP
DATE	:	October 2, 2007
SUBJECT	:	Oncology U.S. Patent Appln. Serial No. 10/626,246 for *Embolic Coil* Inventor(s): Elliot Our Ref.: 10123/00601

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Attorney Docket No. 10123/00601 (03-087)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)	:	Elliot
Serial No.	:	10/626,246
Filing Date	:	July 24, 2003
For	:	Embolic Coil
Group Art Unit:	:	3731
Confirmation:	:	1009
Examiner	:	Elizabeth Houston

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By: Oleg F. Kaplun, Reg. No. 45,559 Date: October 2, 2007

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In response to the Notice of Appeal filed on August 2, 2007, transmitted herewith please find an Appeal Brief for filing in the above-identified application. Please charge the Credit Card of **Fay Kaplun & Marcin, LLP** in the amount of $510.00 (PTO-Form 2038 is enclosed herewith). The Commissioner is hereby authorized to charge the **Deposit Account of Fay Kaplun & Marcin, LLP NO. 50-1492** for any additional required fees. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: October 2, 2007

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PATENT
Attorney Docket No.: 10123 - 00601

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	
Elliot	
Serial No.: 10/626,246	Group Art Unit: 3731
Filed: July 24, 2003	Examiner: Elizabeth Houston
For: EMBOLIC COIL	**Board of Patent Appeals and Interferences**
Confirmation: 1009	

Mail Stop: Appeal Brief - Patents
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed August 2, 2007, and pursuant to 37 C.F.R. § 41.37, Appellant presents this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1, 2, 5 - 12, 24 and 26 in the Final Office Action dated April 25, 2007. The appealed claims are set forth in the attached Claims Appendix.

1. Real Party in Interest

This application is assigned to Boston Scientific Scimed, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 1, 2, 5 - 12, 24 and 26 stand rejected in the Final Office Action. Claims 3, 4 and 25 have been canceled. Claims 13 - 23 have been withdrawn. The final rejection of claims 1, 2, 5 - 12, 24 and 26 is being appealed.

4. Status of Amendments

All amendments filed subsequent to the final rejection have not been entered.

5. Summary of Claimed Subject Matter

The present invention describes, in one aspect, as recited in claim 1, an embolic coil 16 to be positioned at a desired location within a blood vessel. *See* Specification, p. 2, ¶ 19; Figs. 1a, 1b, 1c. Once the coil 16 has reached the desired position within the vascular system, it may be deployed to its operative configuration so that it will remain in position. *Id.* at p. 2, ¶ 20. A primary coil 20 forms the basic element of embolic coil 16, and is wound into another coiled shape to form a secondary coil 18 to give an overall shape to the embolic coil 16. *Id. See also* Fig. 1c. The embolic coil 16 may also include a plurality of fibers 22 that extend from its surface in order to increase the surface area of the coil that is in contact with the flow of blood, making the coil 16 more efficient at slowing the flow of blood therethough. *Id.* at p. 2, ¶ 21; *see also* Fig. 1c. The fibers 22 may be held in place by friction between the loops of the primary coil 20, such

that a certain amount of pressure between the loops is necessary to retain the fibers 22 therebetween. *Id. See also* Fig, 4b.

In another aspect, as recited in claim 24, the present invention describes a coiled medical device 116 for implantation in a patient comprising a core wire 100 made of shape memory material, such as Nitinol, formed in the shape of a secondary coil 106. *Id.* at p. 3, ¶ 29; Fig. 5a. It is generally understood by those in the art that shape memory refers to the ability of a structure to revert to an originally memorized shape after plastic deformation by heating it above a critical temperature. *Id.* at p. 3, ¶ 32. A second wire 104 may be wound around a straightened and stretched memory wire 100 to assume the shape of a primary coil 108. *Id.* at p. 3, ¶ 30; Figs. 5c and 5d. Upon completion of the winding of wire 104 over memory wire 100, wire 100 is released and heated above its critical temperature to revert to its originally memorized shape such that the shape of primary coil 108 is superimposed on the outline of the larger, more complex shape of secondary coil 106 to form embolic coil 116. *Id.* at p. 3, ¶ 31; Fig. 6. Fibers may be added to the primary coil 108 to increase the thrombogenicity of the coil 116. *Id.* at p. 4, ¶ 36.

6. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1, 2, 5,-11, 24 and 26 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,980,514 to Kupiecki at al. (hereinafter "Kupiecki") in view of U.S. Patent No. 6,287,318 to Villar et al. (hereinafter "Villar").

II. Whether claims 5 and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over Kupiecki in view of U.S. Patent No. 6,171,326 to Ferrera (hereinafter "Ferrera").

7. Argument

I. The Rejection of Claims 1, 2, 5 - 11, 24 and 26 Under 35 U.S.C. § 103(a) as Obvious Over Kupiecki in View of Villar Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 1, 2, 5 - 11, 24 and 26 were rejected under 35 U.S.C. § 103(a) as obvious over Kupiecki in view of Villar. (*See* 4/25/07 Office Action, p. 2). Kupiecki discloses a retaining device comprising a wire 202 wound into a primary helix over an inner core member 204. *Kupiecki*, col. 14, ll. 2-7; Fig. 8. The inner core member 204 and primary helix are also wound into a secondary geometry. *Id.* at col. 14, ll. 7-9. The inner core member 204 is chosen such as to provide requisite shape memory and stiffness. *Id.* at col. 14, ll. 33-35.

In the Final Office Action the Examiner acknowledges that Kupiecki does not disclose that the coil has fibers. *See* 4/25/07 Office Action, p. 2. However, the Examiner cites Villar to cure this deficiency. *Id.* Villar discloses a vasso-occlusive device 120 with a helically-wound coil member 122 formed of a biocompatible metallic material. *Villar*, col. 3, ll. 52-58; col. 4, ll. 48-52; Fig. 2. Coil 122 has a constant diameter but is "somewhat more stretched" so that fibrous elements 126 and 128 are looped through the turns of the coils. *Id.* at col. 4, ll. 49-54. Looping filaments 126 and 128 lower the overall effective diameter of the coil making it easier to deliver through a delivery catheter. *Id.* at col. 4, ll. 54-58.

B. The References do not Disclose an Embolic Coil Comprising a Primary Coil and a Secondary Coil in Combination With a Plurality of Fibers Gripped Between Adjacent Coils of the Primary Coil as Recited in Claims 1 and 24

Claim 1 recites an embolic coil comprising, "an elongated core element formed of a shape

memory material treated to define a memorized secondary coil shape" and "an elongated outer element wound around the elongated core element to define a primary coil shape of the embolic coil" in combination with "a plurality of fibers *gripped between* adjacent coils of the primary coil."

In the final rejection, the Examiner acknowledges that Kupiecki does not disclose a coil having fibers as recited in claim 1 and cites Villar to cure this deficiency. However, it is respectfully submitted that Villar does not cure this deficiency because it does not teach or suggest "a plurality of fibers *gripped between* adjacent coils of the primary coil," as recited in claim 1.

In fact, Villar specifically teaches away from fibers that are gripped between adjacent coils. This particular embodiment is described as having coils that are "more stretched." *Id.* at col. 4, ll. 49-54. "Stretched" coils are incapable of gripping fibers between them as they will not provide the necessary pressure to keep the fibers in place. The term "gripped" is defined as "to secure and maintain a tight hold on; seize firmly" according to the *American Heritage Dictionary of the English Language, Fourth Edition.* The primary coil will be unable to "secure and maintain a tight hold" on the fibers between its adjacent coils if the coils are not tightly wound together. In this embodiment, Villar has made clear that the coils are stretched, not tightly wound, and that the fibers are only loosely looped through the coils.

In addition, Villar specifically describes attaching the fibers to the core member by glues or by heating the polymers to maintain contact with the core member 122. *Villar* at col. 5, ll. 21-26. Any attachment would thus exist only at the point which the fiber touches the core member 122. As can be seen in Fig. 2, such contact exists on the inner curve of the looped coil, and not *between* the adjacent coils.

Therefore, it is respectfully submitted that neither of the cited references provided to

those of skill in the art any motivation for the modification suggested by the Examiner and it is respectfully submitted that claim 1 is not rendered obvious by Kupiecki and Villar taken either alone or in combination and that this rejection should be reversed. Because claims 2 and 5 - 11 depend from, and therefore include, all of the limitations of claim 1, it is respectfully submitted that the rejection of these claims should also be reversed.

Claim 24 recites a coiled medical device for implantation in a patient comprising, "a primary coil having a primary coil shape, the primary coil defining a lumen extending therethrough" and "a secondary coil formed of a shape memory material and disposed in the lumen , the secondary coil having a secondary coil memorized shape, wherein, when heated to a temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape" in combination with "a plurality of fibers *gripped between* adjacent coils of the primary coil."

For at least the same reasons as stated above in regard to the § 103(a) rejection of claim 1, it is respectfully submitted that claim 24 is also not rendered obvious by Kupiecki and Villar taken either alone or in combination and that this rejection should also be reversed. Because claim 26 depends from, and therefore includes, all of the limitations of claim 24, it is respectfully submitted that this claim is also allowable and the rejection of this claim should be reversed.

II. The Rejection of Claims 5 and 12 Under 35 U.S.C. § 103(a) as Being Obvious over Kupiecki in view of Ferrera Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, claims 5 and 12 were rejected under 35 U.S.C. 103(a) as obvious over Kupiecki in view of Ferrera (See 4/25/07 Office Action, p. 4). The Examiner stated that Kupiecki discloses all of the limitations of the instant invention substantially as claimed

except for applying cold work to the outer element and the outer element comprising a platinum wire co-wound with a shape memory material. *Id.* The Examiner cites Ferrera to cure these deficiencies. Ferrera discloses a helically wound vasoocclusive coil 1 comprising a distal portion 8 having a second operable, three dimensional shape for filling the anatomical cavity at the site in the vasculature to be treated, and a proximal portion having a second operable, substantially linear shape for filling and reinforcing the distal, three dimensional shaped portion when the vasso-occlusive is implanted at the site in the vasculature to be treated. *Ferrera*, col. 6, ll. 33-40. The vasso-occlusive coils may be formed from a multi-stranded microcable in order to prevent kinks and breakage. *Id.* at col. 6, ll. 47-49 and col. 7, ll. 5-10.

B. The References do not Disclose an Embolic Coil Comprising a Primary Coil and a Secondary Coil in Combination With a Plurality of Fibers Gripped Between Adjacent Coils of the Primary Coil as Recited in Independent Claim 1

Claim 1 has been recited above and discussed with reference to Kupiecki in view of Villar. It is respectfully submitted that Ferrera does not cure the deficiencies of Kupiecki described above in regard to independent claim 1. Specifically, Ferrera does not show or suggest "a plurality of fibers *gripped between* adjacent coils of the primary coil," as recited in claim 1. Because claims 5 and 12 depend from, and therefore include, all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable and the rejection of these claims should be reversed.

8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 1, 2, 5 - 11, 24 and 26 are allowable.

Respectfully submitted,

Date: October 2, 2007

By: _____
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CLAIMS APPENDIX

1. (Previously Presented) An embolic coil comprising:

an elongated core element formed of a shape memory material treated to define a memorized secondary coil shape;

an elongated outer element wound around the elongated core element to define a primary coil shape of the embolic coil; and

a plurality of fibers gripped between adjacent coils of the primary coil.

2. (Original) The embolic coil according to claim 1, wherein the shape memory material of which the elongated core element is formed is, at an operational temperature of the embolic coil, in an austenitic phase.

3. (Canceled)

4. (Canceled)

5. (Original) The embolic coil according to claim 1, wherein a shape of the primary coil is defined by applying cold work to the elongated outer element.

6. (Original) The embolic coil according to claim 1, wherein the memorized shape of the elongated core element is substantially a coil.

7. (Original) The embolic coil according to claim 1, wherein the memorized shape of the elongated core element is substantially a three dimensional spiral.

8. (Original) The embolic coil according to claim 1, wherein the shape memory material of which the elongated core element is formed includes Nitinol.

9. (Original) The embolic coil according to claim 1, wherein the elongated outer element is formed of platinum.

10. (Original) The embolic coil according to claim 1, wherein the primary coil shape is a substantially cylindrical coil.

11. (Original) The embolic coil according to claim 1, further comprising a plurality of fiber retention grooves formed of the elongated core element.

12. (Original) The embolic coil according to claim 1, wherein the elongated outer element comprises a platinum wire co-wound with a wire formed of a shape memory material.

13. (Withdrawn) A method of forming an embolic coil, comprising the steps of:

imparting a memorized shape to a core element formed of a shape memory material, wherein the memorized shape defines a secondary coil of the embolic coil;

straightening the core element;

winding an elongated outer element around the straightened core element to form a primary coil of the embolic coil; and

releasing the straightened core element when the device has been positioned at a deployment location to form the secondary coil of the embolic coil.

14. (Withdrawn) The method according to claim 13, further comprising the step of attaching fibers to the embolic coil.

15. (Withdrawn) The method according to claim 14, wherein the fibers are attached to the primary coil.

16. (Withdrawn) The method according to claim 14, wherein the fibers are attached to

grooves formed in the core element.

17. (Withdrawn) The method according to claim 13, further comprising the step of cooling the shape memory core element below a critical temperature before straightening the core element.

18. (Withdrawn) The method according to claim 13, wherein the core element is released in an environment having a temperature above a critical temperature of the shape memory material.

19. (Withdrawn) The method according to claim 13, wherein the secondary coil shape is one of a spiral, helix, vortex, and three-dimensional spriral.

20. (Withdrawn) The method according to claim 13, wherein the elongated outer element is formed of a platinum wire.

21. (Withdrawn) The method according to claim 20, further comprising the step of co-winding the platinum wire with wire formed of a shape memory material.

22. (Withdrawn) The method according to claim 13, wherein the core element is formed of a Nitinol wire.

23. (Withdrawn) The method according to claim 13, further comprising the step of forming fiber retention grooves in the core element.

24. (Previously Presented) A coiled medical device for implantation in a patient comprising:

a primary coil having a primary coil shape, the primary coil defining a lumen extending therethrough;

a secondary coil formed of a shape memory material and disposed in the lumen, the secondary coil having a secondary coil memorized shape, wherein, when heated to a

temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape; and

a plurality of fibers gripped between adjacent coils of the primary coil.

25. (Canceled)

26. (Original) The medical device according to claim 24, wherein the shape memory material includes Nitinol.

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

Serial No.: 10/626,246
Group Art Unit: 3731
Attorney Docket No.: 10123 - 00601

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.